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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,856	12/02/2003	Shiguang Yu	2664H-000059/US	3241
7590 Martin B. Barancik COLGATE-PALMOLIVE COMPANY 909 River Road P.O. Box 1343 Piscataway, NJ 08855-1343			EXAMINER EBRAHIM, NABILA G	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 01/24/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/725,856	<b>Applicant(s)</b> YU ET AL.	
	<b>Examiner</b> Nabila G. Ebrahim	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 October 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 15-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 37-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt of Applicant's remarks and amendments to the claims dated 10/26/07 is acknowledged.

#### ***Status of Claims***

Claims 1-38 are pending in the application.

Claims 15-36 are withdrawn from consideration.

Claims 1-14 and 37-38 are under current examination.

***Status of Office Action:*** Final.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 10-12 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Morris et al. US publication 20010014442 (Morris).

Morris teaches consumable product utilized to maintain and restore hair color comprises a substrate and an effective amount of a directly available amino acid (in pure or diluted form) wherein the directly available amino acid is selected from the group consisting of tyrosine, phenylalanine and mixtures thereof (abstract). The effective amount of directly available tyrosine may be at least approximately 0.05% by weight of the diet [0019]. Also adding an effective amount (e.g., at least approximately 0.05% by weight, or at least approximately 0.1% by weight) of a directly available amino

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acid selected from the group consisting of tyrosine, phenylalanine and mixtures thereof or to an animal consumable product having indirectly available amino acids therein to produce a supplemented consumable [0021], it is noted that the range disclosed by Morris is overlapping with range required in instant claims 1-3. The composition is provided to animals such as e.g., a cat, a dog, or mink, etc. [0026]. The food can be gelatin based [0030, 0037, 0038, and 0041]. Morris also discloses that milk contains proteins supplying adequate amounts of phenylalanine and tyrosine for melanin synthesis [0047]. The animal food can be in a dry matter [0036, 0047].

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-14, 37 and 38 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. US publication 20010014442 (Morris) in view of Gerth et al US 5925377 (Gerth) and further in view of Nagaoka Satoshi et al., Effects of excess dietary tyrosine on cholesterol, bile acid metabolism and mixed-function oxidase system in rats, J Nutr. 1990 Oct;120(10):1134-9.

Morris is relied upon for the reasons set forth hereinabove.

The reference discloses the use of fat, cellulose (fibers), carbohydrate (sucrose and starch), and protein in the animal food [abstract, and table 3]. Morris did not disclose the amounts recited in claims 5 and 9; however, animal foods ingredients such as proteins, carbohydrates, fats, and dietary fibers are conventional ingredients that are known to be used in many different amounts and ranges. Furthermore, once a method of using an ingredient is known it is within the skill of the skilled artisan to determine the optimum amounts to use and the optimum end points in using the ingredient.

Morris is deficient in disclosing the use of the composition for weight loss and also the improvement of the method of use by reducing the amount of tyrosine.

Gerth teaches that a dietary supplement composition wherein DL-phenylalanine is combined with tyrosine to act as an appetite depressant (abstract).

It would have been obvious to one of ordinary skill in the art to combine the disclosures of Morris and Gerth to control the obesity problems in animals/humans.

Both references do not disclose a reason of why the skilled artisan would be motivated to lower the amount of tyrosine.

Satoshi teaches that the excess dietary tyrosine causes hypercholesterolemia and affects bile acid metabolism and mixed-function oxidase system (title and abstract). The reference does not specify that the amount of tyrosine used should not exceed the ranges recited in the instant claims. However, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of tyrosine in order to best achieve the desired results.

Accordingly, it would have been obvious to one of ordinary skill in the art to reduce the amount of tyrosine used by Gerth to the least amount that may be useful to control appetite and assists in weight loss in animals and reduce any side-effects that may result from the use of higher tyrosine. The expected results would be a composition that includes tyrosine in a least amount that may cause appetite suppression as the overlapping amount disclosed by Morris, phenylalanine, carbohydrate, protein, fat, and dietary fibers. The skilled artisan would be motivated to lower the amount disclosed by

Gerth because of the research disclosed by Satoshi that excess amount of tyrosine would increase blood cholesterol. The skilled artisan would have expectation of success of having a dietary supplement comprising tyrosine that reduces weight and is improved to include less amounts of tyrosine.

***Response to Arguments***

6. Applicant's arguments filed 10/26/07 have been fully considered but they are not persuasive.

**Claim Rejection under 35 U.S.C. §102:**

**Applicant argues that:** The disclosure of a range is no more a disclosure of the end points than it is a disclosure of each intermediate point. To anticipate, a disclosed range must teach the claimed range with sufficient specificity. M.P.E.P. § 2131.03(II).

Applicants' claimed range of tyrosine concentration fits into the disclosed range more than seven times over. The broad range disclosed by Morris et al. cannot be said to teach Applicants' narrow range that is nestled-away at a remote end of the disclosed range and that is surprisingly important for appetite and weight control.

**To respond:** the range taught by Morris overlaps with the range recited by the instant claims. Claim 1 recites a range which does not exceed 0.4%, this is interpreted as including from about 0.0%, Morris disclosed a range of at least approximately 0.05% by weight; or at least approximately 0.1%, accordingly, the overlap is equal to 0.3 to 0.35% which is between 75% to 87.5% of the small range recited in claim 1. It is the position of the Examiner that this wide overlap (a range that overlaps 3/4 or more of the instant range) reads on the sufficient specificity required by M.P.E.P.

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Claim Rejection under 35 U.S.C. §103:

**Applicant argues that:** Morris et al. discloses a food product or consumable product that can contain anywhere from 0.05% to 3% by weight tyrosine, with 1% to 3% being preferred (Morris et al. [0034]).

**To respond:** as shown hereinabove, though the whole range of Morris is higher, it is still overlapping with the ranges recited in the instant claims by a percentage of at least 75%.

**Applicant argues that:** as far as Applicants are aware, Nagaoka et al. is silent concerning the effect of tyrosine on appetite regulation and weight control and the Office has not pointed to any such teaching in Nagaoka et al. Indeed, Example 1 of the cited reference indicates that the food intake of rats fed an excess of tyrosine diet was no different from that of rats fed a control diet (Nagaoka et al. at 1136).

**To respond:** instant claims recite a composition wherein the intended use of the composition of the prior art could have caused regulation of appetite and weight control. Note also that the reference is considered for its entirety and not only for one example.

**Applicant argues that:** the Office does not point to anything in the prior art recognizing tyrosine concentration, or minimization thereof, as a result effective for appetite suppression or weight control. The Office supports the rejection with a single sweeping conclusory statement: However, the amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize".



**To respond:** Morris discloses an overlapping range of tyrosine in the composition, Gerth teaches that a dietary supplement composition wherein DL-phenylalanine is combined with tyrosine to act as an appetite depressant. Note that, once a method of using a compound is known it is within the skill of the skilled artisan to determine the optimum amounts to use and the optimum end points in using the compound.

**Applicant argues that:** given the very large percentages of tyrosine, the skilled artisan of the day reading Gerth et al. and seeking to develop an edible composition for appetite regulation or weight control would not have contemplated even experimenting with tyrosine levels as low as 0.4% as claimed - a level 32x lower than the amount of tyrosine and 95x lower than the amount of phenylalanine expressly disclosed by Gerth et al. - which level Applicants were the first to discover as key for appetite regulation and weight control.

To respond: if a skilled person in the art would find that a specific composition is sufficient since it treats a specific problem and accordingly the artisan is discouraged to do any further experimentation, pharmaceuticals would not have ever improved and new compounds to treat the specific problem would not have ever been discovered. In addition, Satoshi discussed the reasons why a person should avoid having high percentage of tyrosine in diet (for fear of occlusion of arteries by hypercholesterolemia). Further, Gerth composition led to the same results aimed by the instant claims while Applicant did not show unexpected results of the specific range which Applicant is arguing.

**Applicant argues that:** to the best of Applicants' knowledge, Nagaoka et al. is silent on the connection, if there is any, between excess dietary tyrosine, serum cholesterol and appetite suppression or weight control, and the Office does not point out any such connection. As such, Applicants respectfully submit that Nagaoka et al. neither cures the teaching-away of Gerth et al. nor does it provide the necessary reason why one of skill in the art would be motivated to lower the amount of tyrosine to achieve appetite suppression or reduce food intake in an animal either taken alone or in view of Greth and Morris.

**To respond:** Satoshi has been relied upon because the reference teaches that the excess dietary tyrosine causes hypercholesterolemia and affects bile acid metabolism and mixed-function oxidase system (title and abstract). It is a public knowledge that compounds and dietary components that cause hypercholesterolemia should be avoided because of the its risk on the heart, brain and other organs. Accordingly, the reference provides a reason why the skilled artisan would be motivated to lower the amount of tyrosine. This is Applicant's main concern in the arguments.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER